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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/836,477 | 04/18/2001 | Brendan Larder | VIP0011 | 8810 |
| 23377 | 7590 | 04/20/2006 | EXAMINER | |
| WOODCOCK WASHBURN LLP ONE LIBERTY PLACE, 46TH FLOOR 1650 MARKET STREET PHILADELPHIA, PA 19103 | | | | CLOW, LORIA |
| | | ART UNIT | | PAPER NUMBER |
| | | 1631 | | |

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/836,477 | LARDER ET AL. | |
| | Examiner | Art Unit | |
| | Lori A. Clow, Ph.D. | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 January 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4, 8, 13, 16-25, 28-32 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4, 8, 13, 16-25, 28-32 and 39-41 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Applicants' response, filed 30 January 2006, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 5-7, 9-12, 14, 15, 26, 27, 33-38 and 42 have been cancelled. Claims 1-4, 8, 13, 16-25, 28-32 and 39-41 are currently pending.

Claim Rejections - 35 USC § 101

Non-Statutory Subject Matter

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 8, 13, 16-25, 28-32 and 39-41 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, for the reasons set forth in the previous Office Action and expanded upon below.

The method and computer program of the instant claims is directed determining a phenotype comprising obtaining genetic sequence data, identifying a mutation pattern, searching a database, obtaining a database phenotype, and determining a phenotype of the sequence based upon the database phenotype. The claims do not produce a result which is concrete, tangible, and useful. The claims merely encompass manipulations of abstract ideas (data) without producing a specific output that meets the concrete, tangible, and useful criteria. No specific outcome is set forth in the claims such that the steps of the method produce a result that is

immediately concrete, tangible, and useful. The claims must, as a whole, satisfy section 101 and must be for practical application, which can be defined as:

1. The claimed invention “transforms” and article or physical object to a different state or thing.

[The claimed invention in the instant case does not transform any physical object or article.

Even though Claim 4 provides a step wherein the Human Immunodeficiency Virus is obtained from at least one of a plasma sample, a blood sample, a saliva sample, mucous sample, and a tissue sample, it does not clearly describe a physical step as it is not apparent where this step occurs in the method.]:

2. The claimed invention otherwise produces a useful, concrete, and tangible result, based upon various factors (see below) *[The claimed invention in the instant application does not produce a concrete, tangible, and useful result].*

Practical Application That Produces a Useful, Concrete, and Tangible Result

For eligibility analysis, physical transformation “is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application.” AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452... In determining whether the claim is for a “practical application,” the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is “useful, tangible and concrete.” (1) “USEFUL RESULT” For an invention to be “useful” it must satisfy the utility requirement of section 101. The USPTO’s official interpretation of the utility requirement provides that the utility of an invention has to be (i) specific, (ii) substantial and (iii) credible. MPEP § 2107 and Fisher, 421 F.3d at __, 76 USPQ2d at 1230 (citing the Utility Guidelines with approval for interpretation of “specific” and “substantial”). (2) “TANGIBLE RESULT” The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had “no substantial practical application.”). “[A]n application of a law of nature or mathematical formula to a ... process may well be deserving of patent protection.” Diehr, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also Corning, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 (“It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . .”). In other words, the opposite meaning of “tangible” is

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“abstract.” (3) “CONCRETE RESULT” Another consideration is whether the invention produces a “concrete” result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. *In re Swartz*, 232 F.3d 862, 864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000) (where asserted result produced by the claimed invention is “irreproducible” claim should be rejected under section 101). The opposite of “concrete” is unrepeatable or unpredictable.

Descriptive material can be characterized as either “functional descriptive material” or “nonfunctional descriptive material”. In this context, “functional descriptive material” consists of data structures and computer programs which impart functionality when employed as a computer component (The definition of “data structure” is “a physical or logical relationship among elements. Designed to support specific data manipulation functions.” The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993)). “Nonfunctional descriptive material” includes, but is not limited to, music, literary works and a compilation or mere arrangement of data.

Both types of “descriptive material” are nonstatutory when claimed as **descriptive material per se**. *Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759. When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. When nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material, i.e., **abstract ideas**, stored in a computer-readable medium, in a computer, or on an electromagnetic carrier signal does not make it statutory. See *Diehr*, 450 U.S. at 185-86, 209

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USPQ at 8 (noting that the claims for an algorithm in Benson were unpatentable as abstract ideas because “[t]he sole practical application of the algorithm was in connection with the programming of a general purpose computer.”) Such a result would exalt form over substance.

In re Saker, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978)...

Applicant is invited to view the following web site for the text of the new Interim Guidelines of November 2005:

http://www.uspto.gov/web/offices/pac/dapp/ropa/preognotice/guidelines101_20051026.pdf

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 8, 13, 16-25, 28-32, and 39-41 remain rejected under 35 U.S.C. 102(a) as being anticipated by Hertogs et al. for the reasons set forth in the previous Action.

The Declaration under 37 CFR 1.131 is insufficient to overcome the prior art rejection under 35 USC 102(a) over Hertogs et al. (Antimicro. Agents and Chemo. (March 2000) Vol. 44, pages 568-573), as it is not signed by all named inventors.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG

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30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

April 16, 2006
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow

Ardin H. Marschel 4/17/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER